Support2Quit Study Protocol

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A. SIGNIFICANCE

Smoking is the leading cause of preventable death in the U.S., accounting for approximately 443,000 deaths, which is 20% of all deaths annually. Despite overall declines in the rate of tobacco use in the United States over the past 30 years, improving quit rates among current smokers continues to be a significant public health focus given the high risk for long-term negative health outcomes. There has been extensive research evaluating a wide range of smoking cessation approaches over the past 40 years, and the 2008 Clinical Practice Guideline for treatment of tobacco use and dependence summarized the efficacy of smoking cessation approaches based on more than 8700 research articles. Although there has been significant progress in the application of both clinical and public health interventions aimed at smoking cessation, researchers have concluded that the overall success rate of these interventions has not shown significant improvement. New, innovative, theory-driven approaches are needed to both improve the overall abstinence and long-term quit rates, as well as to increase the reach of effective interventions.

One theory-driven approach that has shown promise as a basis for intervention development is cognitive dissonance induction. Cognitive dissonance theory is based on the premise that individuals strive toward consistency between their beliefs and behaviors. When *inconsistencies* between attitudes, beliefs or behaviors occur, individuals tend to adjust their beliefs or behaviors in order to reduce the discomfort of the dissonance that is elicited by the inconsistency. Reducing cognitive dissonance can be achieved in one of three ways: 1) adjusting one or more attitudes or behaviors to make the relationship between the two consistent, 2) acquiring new information that offsets the dissonant belief, or 3) reducing the importance of the attitudes or beliefs so that the inconsistent behavior can continue.

Interventions that use cognitive dissonance to elicit behavior change do so through situations that create high levels of cognitive dissonance. Regardless of the behavior being targeted, there are several common concepts that are central to effective cognitive dissonance induction. First, participation in the induction activity must be voluntary. Voluntary participation requires the individual to attribute the inconsistency between beliefs and behaviors as existing within themselves, rather than being due to demands of a given situation. Effortful involvement (i.e., actively engaging in treatment exercises) is also required, and is believed to result in greater dissonance and greater motivation for change. And finally, public statements of beliefs (i.e., counter-attitudinal advocacy) are thought to elicit heightened dissonance responses. In fact, Roehrig et al have shown counter-attitudinal advocacy to be successful in isolation of the other dissonance-inducing components (voluntariness, effortful involvement). Counter-attitudinal advocacy activities that are often used to induce dissonance include preparing and delivering speeches or statements about personal beliefs, role-plays where individuals act out a particular behavior, or making public commitments. Given the central role that counter-attitudinal activities appear to play in eliciting cognitive dissonance, these activities are a core component of the proposed cognitive dissonance mobile app intervention.

Cognitive dissonance has been widely researched and applied in the physical and mental health arenas. In particular, increasing cognitive dissonance has been shown to be successful at treating obesity,[3] improving healthy eating, reducing fears, treating chronic illness, improving safe sex practices, and has been used as a preventive measure in the development of eating disorders. In their study of eating disorders, Stice and colleagues showed that participants in a cognitive dissonance induction intervention who voluntarily critique the thin beauty ideal in verbal, written, and behavioral exercises (voluntariness, counter-attitudinal advocacy) resulted in significant reductions in the thin-ideal internalization, which putatively decreased body dissatisfaction, unhealthy dietary behaviors, negative affect, and eating disorder symptoms.

Of particular relevance, cognitive dissonance approaches have also shown success in treating substance use, reducing the initiation of smoking, and improving short-term outcomes for smoking cessation. In one study, Simmons et al. demonstrated greater quit rates at one-month follow up for smokers who engaged in video-taped discussions of the consequences of smoking delivered via computer. Although prior study results are promising, no long-term significant outcomes have been found, which suggests that increased exposure to dissonance induction activities (dosage) and reach of cognitive dissonance induction approaches might yield improved smoking abstinence outcomes. Guided by prior research, the proposed cognitive dissonance intervention (CDI) specifically provides increased opportunity for exposure to cognitive dissonance by including dissonance induction activities in each of the proposed modules. In particular, we propose to offer the participant multiple opportunities for counter-attitudinal activities and public statements. Additionally, the mobile app format allows for increased access and reach of the intervention. The CDI app will be based on prior cognitive dissonance intervention activities that have demonstrated effectiveness and will specifically

build on consultant Simmons' prior work with cognitive dissonance induction via video-recorded tasks for smoking cessation.

A.1. Mobile behavioral health-based interventions

The utilization of mobile applications for smoking cessation and other addictive behaviors has increased over the past several years due to the low cost, ease of use, and increased availability via smartphones. Smartphone use has grown considerably in recent years, with more than 90% of adults in the U.S. currently estimated to be relying on smartphones daily, and as mobile phone data plans have become less costly, many of these individuals have turned to their mobile devices as their primary internet connection. Use of mobile apps has continually increased over the past several years and it is currently estimated that US adults spend an average of nearly 3 hours per day doing non-voice related activities on their smartphones and have an average of 80 apps. In addition, within the past three years, watching and recording videos has become commonplace on mobile phones, with an estimated 75% of people using their smartphones to record and access video.

One of the primary benefits of mobile app interventions is the ability to provide support for introducing new skills and for mobile content to be more readily delivered (pushed) to participants when and where they need it. Mobile interventions proactively *push* content to participants without requiring them to visit a computer. The proactive outreach of mobile interventions is especially critical given the limited use (engagement) of websites found in tobacco cessation interventions.

The term *mHealth* has even been coined to refer to programs that are delivered via mobile communication devices. While the term "mobile" has come to describe portable technology devices, Beale has asserted that the *user* is mobile, not just the technology: "…it is about computing for users who are not in a single location, but are moving around…computing whilst on the go as well as when at their destinations." We propose to use automated text messaging to extend the reach and impact of the intervention.

Little research has been reported on the effects of mobile behavioral-health-based interventions for smoking cessation, but the results that are available have been promising. Although NCI public health initiatives (e.g., QuitGuide, QuitSTART) are currently available, they have not been evaluated for efficacy. Given the increased reach of mobile-based interventions, coupled with evidence that internet-based delivery systems might be an effective method for delivering cognitive dissonance interventions, suggests that a cognitive dissonance mobile app for smoking cessation might be a feasible and novel treatment approach. It is important to note that even modest absolute abstinence rates can translate into very significant public health impact (reach X efficacy) given the large number of tobacco users who could be reached through mobile interventions.

A.2. Using technology-based delivery methods

Overall, the high cost and labor-intensive nature of face-to-face interventions has made the development and testing of electronically-delivered treatments an attractive modality due to their affordability and potential for dissemination. Such interventions have been successfully utilized for behavior change and for the treatment of mental health problems, including depression, fears, healthy eating and smoking cessation. Computer and mobile app-based interventions offer increased accessibility and flexibility, as well as greater confidentiality and anonymity, all of which increase the number of individuals that can be treated.

There is a growing body of reports and published studies that have described encouraging results for web-based interventions for smoking cessation and a recent meta-analysis of RCTs for smoking cessation concluded that there is sufficient clinical evidence to support the use of web- and computer-based smoking cessation programs for adult smokers. Additionally, a number of computer-based cognitive dissonance interventions have been developed and tested. For example, in their study of female college students with body dissatisfaction, Stice, Durant, Rohde & Shaw evaluated the use of an internet-based program for the prevention of eating disorders. This study found that the internet-based participants showed significant reductions in eating disorder risk factors and symptoms compared to the control conditions at 1- and 2-year follow-ups. More recently, Chithambo and Huey developed and tested an eating disorder prevention intervention delivered in a web-based format. Results indicated that both of the internet-based interventions produced significantly greater reductions in body dissatisfaction, thin-ideal internalization, and depression compared to the no intervention control condition.

Although it is difficult to draw strong conclusions from the emerging research on electronically delivered interventions because of the limited number of studies and differences in methodologies – including the extent to which online programs were supplemented by counseling (in-person or phone calls) or pharmaceutical supplements – overall conclusions of these meta-analyses support the superiority of web-based interventions compared to non-web-based interventions across a broad range of health behaviors. However, despite

positive preliminary evidence supporting computerized smoking cessation interventions, further research is needed. In fact, a recent Cochrane meta-analysis of web-based cessation studies concluded that "…more rigorous studies comparing the long-term effects of Internet interventions with non-Internet interventions or no intervention at all are needed in order to determine the true long-term effectiveness of the internet as a tool for smoking cessation."

A.3. Description of the CoQuit mobile app prototype

The CoQuit mobile app prototype was developed during Phase I and was designed to build on previous tobacco cessation treatment conducted by Co-I Severson and Consultant Simmons, on the substance abuse cessation and mobile-app treatment research conducted by PI Smith and Co-I Severson, and on the cognitive dissonance intervention research by the project consultant Simmons. The primary goal of the CoQuit app was to induce cognitive dissonance through a series of group-based mobile app activities with the overall goal of decreasing cigarette use and increasing overall quit rates. As outlined previously, three concepts are central to eliciting cognitive dissonance: voluntariness, effortful involvement, and counter-attitudinal advocacy. Based on the strong relationship between counter-attitudinal advocacy and cognitive dissonance found in previous studies, we requested participants make a public statement – either in letter format or verbal statements to family and friends – in each module as well. In addition to the cognitive dissonance instruction modules, users received two smoking cessation "tips" per day. Access to each successive module were "unlocked" as users moved through the modules (i.e., module 2 was unlocked following completion of module 1, etc.). Once a module was "unlocked" users were able to access each of the training and practice components as often as wanted or needed. Development of the prototype app included 6 video-based modules, each of which presented instructions for a smoking cessation "activity" that users were required to record using their phone and then post within the app. For example, module 1 gave instructions via a video narrator for users to record and upload a video of themselves stating their name and how long they had been smoking as an introduction to their group. Successive modules included instructions for choosing a quit date, outlining the pros and cons of their smoking behavior, drafting a letter to a loved one stating their commitment to quit smoking, drafting a letter to an adolescent describing all the reasons they should avoid starting to smoke. Each activity was recorded on the participant's phone and then uploaded to the app for all group members to view. For the prototype, we assigned 8 people to be in each treatment group. Each participant in the group could view the posted video of other group members, and give a "like" to each other's videos.

B. INNOVATION

The proposed project is innovative in three primary ways. First, the proposed CoQuit mobile app will be the first dissonance induction-based mobile app for smoking cessation. Although cognitive dissonance has been shown to be an effective way to motivate smokers to quit, the use of this strategy has largely been limited to group treatment or in person treatments. Our use of a mobile app will be the first program to extend the reach of this intervention and offer the program through the person's smartphone. Second, the proposed study focuses on both quit attempts as well as overall quit rates. The dual focus on increasing quit attempts and smoking cessation rates will help to inform the scientific knowledge of proximal outcomes that might inform intervention efforts aimed at more distal outcomes. And finally, the mobile app-based format – if shown to be successful at improving smoking quit rates – lends itself to improved accessibility. One significant limitation of existing face-to-face cognitive dissonance-based programs is cost and limited access to treatment for individuals without transportation. We believe that our program will be very attractive, as the mobile app-based format can greatly expand reach – both as a standalone program and as an adjunct to existing interventions. The mobile app intervention is also likely to appeal to underserved smokers and younger smokers who use their mobile phones for internet access and who frequently download apps for various personal interests and supports. Given the need for innovative smoking cessation programs that are low-cost and easy to access, the social and public health impact of the proposed CoQuit intervention is high.

C. APPROACH

C.1. Product evaluation.

We will conduct an evaluation of the CoQuit app with a nationwide sample of 500 adults who are daily smokers. Feasibility, usability, participant satisfaction, and intervention outcomes of cigarette use will be evaluated in an efficacy trial. Data on: 1) frequency and duration of app use, 2) number of modules completed, 3) changes in measures of cognitive dissonance, 4) changes in readiness to quit, and 4) changes in smoking attitudes and behaviors (including quit attempts, number of days without smoking, and co-use of other forms of tobacco, including e-cigarettes) will be examined. Participants will be compensated using gift cards to Amazon with $25 each for the baseline, 1-month and for the 3-month assessment. In addition, each participant who completes all three assessments will receive a bonus payment of $50. We estimate that 75% of participants will receive the bonus payments. Participants in the focus groups and usability testing will receive a $50 gift card for their time and effort.

C.2. Study Design. Our evaluation of the CoQuit app will be conducted with 500 adults who are daily smokers who will be recruited through social media. Participants will be randomly and equally assigned to one of two conditions: 1) CoQuit with CDI (cognitive dissonance induction), or 2) CoQuit content without CDI All participants will be instructed to attempt to reduce cigarette use and to identify a target quit date at program initiation. Self-reported cigarette use and readiness to quit will be measured at 1-month and 3-month assessments. In addition, we will measure changes in cognitive dissonance for participants in the CoQuit CDI group. Cognitive dissonance measures will be completed after each cognitive dissonance activity, as well as at each of the baseline, 1-month and 3-month assessments.

C.3 Participants. Details regarding sample characteristics, eligibility criteria, recruitment and retention are described in the Human Subjects. Briefly, participants will include both male and female adult smokers recruited from the United States. We have a long history of successful recruitment of smokers, and have extensive experience utilizing recruitment efforts to enroll smokers and tobacco users in mobile app-based intervention programs. Inclusion criteria will be as follows: 1) age 18 or older, 2) self-reported daily smoking, 3) having a valid home mailing address in the United States, 4) English-speaking, 5) access to a smartphone with video capability for the duration of the project, 6) not currently enrolled in or participating in any tobacco cessation programs, and 7) expressed desire to quit smoking.

Recruitment procedures: Five hundred male and female adult smokers will be recruited from the United States. We have extensive experience recruiting and enrolling adult smokers, and will primarily use Facebook for our recruitment of participants to the evaluation study. We will use ads on Facebook to attract current smokers who might be interested in quitting to click on an ad in their Facebook feed that will take them to a Landing Page which provides some information about the study and some general requirements about their current smoking status. If they click to indicate their interest, they will be taken to a screener to determine their eligibility for the study. If they are eligible for the study, we will send them more complete information on the study and a link to an online consent form.

C.4. Overview of the Proposed Intervention Conditions

We propose to randomize participants into one of two conditions, outlined below.

CoQuit with CDI. Participants who are randomized to the CoQuit with CDI will be sent access information and instructions and access code for downloading the CoQuit CDI app from the app store immediately following their baseline assessment. Once the app is loaded onto their phone, participants will be assigned to a group of 8 daily smokers who are intended to move through the app at a similar pace. The proposed modules will each include an instruction video that outlines a cognitive dissonance inducing activity that participants will be instructed to record and upload to the app for all group members to see. Modules will be “unlocked” in ascending order as participants move through the program (i.e., module 2 will be “unlocked” after a participant completes module 1, etc.). In addition, participants will receive 2 smoking cessations tips per day to assist with reducing cigarette use and increasing motivation to quit.

CoQuit without CDI (comparison condition) Participants who are randomized to the CoQuit without CDI will be sent access information, instructions and an access code for downloading the CoQuit app from the app store immediately following their baseline assessment. Once the app is loaded onto their phone, participants will be free to login and use the app as often as they want. Daily tips and guidance in reducing smoking and increasing motivation to quit will be provided at least once daily. The content and look and feel of this comparison condition will match the CoQuit with CDI but lack any cognitive dissonance activities.

C.5. Data Collection Procedures

C.5.1. Overview and timeline for the evaluation study.

The baseline assessment will primarily measure participant risk factors, as well as past and current cigarette and other tobacco use, readiness to quit, quit attempts and cessation in the past year, and will consist of questionnaires administered using Qualtrics; none of the assessments will be done via the mobile app.

The 1-month assessment will focus on usability, cognitive dissonance, motivation to quit, and short-term outcomes such as making a quit attempt, use of the app (dosage), number of cigarettes smoked, and days abstinent from smoking. For the 3-month assessment, the focus will be on cessation outcomes, including both point prevalence (i.e., no smoking in the past 7 days; no smoking in the past 30 days) and sustained abstinence, which is defined as sustained abstinence between the 1- month and 3- month assessment. We will also assess quit attempts at each assessment. Non-responders to the request to complete a follow up assessment will be sent email and text messages to encourage completion of the assessment. We will continue to prompt completion for 14 days following the initial request for the one month assessment and there will be a 30 day window for completion of the 3-month assessment.

C.5.2. Measures. Program navigation and usability will be assessed during usability testing and for the evaluation participants over the one month of use, and will include reports of: 1) ease of use, 2) perceived benefits of using the app, and 3) suggestions for product development modifications. Participants will also provide ratings on product satisfaction and usability on a 7-point Likert Scale. In addition to qualitative data, login tracking information from the app will be used to assess each participant's: 1) frequency and duration of app use, 2) number of modules completed, and 3) type and frequency of cigarette use. These data will be used to evaluate treatment engagement and adherence, as well as pre- and post- changes in tobacco use.

A full description of measures is included in the Human Subjects. Briefly, the following will be used to examine pre- and post- changes in smoking behavior, cognitive dissonance, and motivation to quit: 1) Nicotine Dependence, 2) Past and Current Tobacco Use (including e-cigarettes), 3) Motivation to Quit, 4) Quit Attempts, and 5) Cognitive Dissonance. Nicotine dependence will be measured at baseline and at each follow-up assessment using the Fagerström Test for Nicotine Dependence and items that assess withdrawal experiences. Past and current tobacco use will be assessed at each time point, including type (including e-cigarettes), frequency, and duration of use. Motivation to quit will be assessed at baseline by asking participants if they want to quit within the next 30 days and at follow-up assessments in terms of stages of change. We will also use an adaptation of the Contemplation Ladder that we have used extensively in our prior research and have found in predicting tobacco cessation. Quit attempts will be measured by the number of intentional quit attempts that last at least 24 hours, duration of quitting, and use of pharmacological adjuncts at each time point. Cognitive dissonance will be measured using the Dissonance Thermometer.Prior research has shown that the 3- item discomfort factor of the Dissonance Thermometer represents the affective expression of cognitive dissonance. Cognitive dissonance will be assessed after each cognitive dissonance activity, as well as at each of the baseline, 1-month and 3-month assessments.